Application Submission and Deadline

On or before *July 3, 1995*, submit the original and two copies of the application (Form PHS 5161–1—OMB Number 0937–0189) and one electronic copy on disk to: Henry S. Cassell III, Grants Management Officer, Procurement and Grants Office, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–16, Atlanta, GA 30305.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are:

A. Received on or before the deadline or

B. Sent on or before the deadline date and received in time for submission to the independent review committee. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable proof of timely mailing.)

2. *Late Applications:* Applications that do not meet the criteria in 1.A. or 1.B. are considered late applications and will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from: Manuel Lambrinos, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–16, Atlanta, GA 30305, telephone (404) 842–6777. Programmatic technical assistance may be obtained from: Sevgi Aral, Ph.D., Division of STD/HIV Prevention, National Center for Prevention Services, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–02, Atlanta, GA 30333, telephone (404) 639–8259.

Please refer to Announcement 523 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''Introduction'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: April 14, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–9879 Filed 4–20–95; 8:45 am]

BILLING CODE 4163–18–P

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for National/Regional Minority Organization Human Immunodeficiency Virus/Sexually Transmitted Diseases Prevention, Immunization, and Tuberculosis Projects—Program Announcement 305b: Amendment of Time and Date

Federal Register Citation of Previous Announcement 60 FR 13728—dated March 14, 1995.

This notice announces an amendment in the time and date of a previously announced meeting.

Previously Announced Time and Date: 8:30 a.m.–4:30 p.m., April 18, 1995.

Amendment in Meeting Time and Date: 8:30 a.m.–4:30 p.m., April 18, 1995. 8:30 a.m.–4:30 p.m., April 19, 1995.

Dated: April 18, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–10009 Filed 4–19–95; 10:14 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95M–0072]

Cardiac Pacemakers, Inc., Premarket Approval of VENTAK® P2 AICD™ System: Model 1625 VENTAK® P2 Pulse Generator, Model 2835 Software Module, and Model 2815 VENTAK® ECD External Cardioverter Defibrillator

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Cardiac Pacemakers, Inc., St. Paul, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the VENTAK® P2 AICD™ System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 10, 1995, of the approval of the application.

DATES: Petitions for administrative review by May 22, 1995.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Carole C. Carey, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION: On August 30, 1993, Cardiac Pacemakers, Inc., St. Paul, MN 55112, submitted to CDRH an application for premarket approval of VENTAK® P2 AICD™ System consists of the following: Model 1625 VENTAK® P2 pulse generator; Model 2835 Software Module to be used with commercially available Cardiac Pacemakers, Inc., (CPI®) Model 2035 Handheld Programmer and Model 6575 or 6577 Telemetry Wand; Model 2815 VENTAK® ECD External Cardioverter Defibrillator (which includes the Model 6873 High Voltage Cable with Model 6838 Thumbscrew, Model 6843 Bipolar Cable with Model 6838 Thumbscrew, Model 6874 Bipolar Cable, and related CPI® commercially available accessories); commercially available CPI® ENDOTAK® 60–Series Lead System and accessories; commercially available CPI® epicardial defibrillation leads and accessories; and commercially available pace/sense leads and accessories. The device is an automatic implantable cardioverter defibrillator system and is indicated for the treatment of patients with ventricular fibrillation and/or ventricular tachyarrhythmias who are at high risk of sudden cardiac death. Such patients are defined as having experienced the following situations: (1) The survival of at least one episode of cardiac arrest presumably due to hemodynamically unstable ventricular tachyarrhythmia not associated with acute myocardial infarction, and/or (2) a poorly tolerated, sustained ventricular tachycardia (VT) and/or ventricular fibrillation (VF) which recurs spontaneously or can be induced despite the best antiarrhythmic drug therapy. Note: The clinical outcome of hemodynamically stable, sustained VT patients is not fully known. A study of the safety and effectiveness of the VENTAK® P2 system on this selected subgroup of VT patients has not been conducted.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this